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10/821,471	04/08/2004	Hironori Kobayashi	11333/37	1081

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/821,471

Applicant(s)

KOBAYASHI, HIRONORI

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/8/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to an apparatus for forming an immobilized sample on a porous membrane, classified in class 436, subclass 514.
- II. Claims 18-21, drawn to a method for quantifying a target substance in an immobilized sample, classified in class 435, subclass 7.92.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to practice another and materially different process such as for isolation or purification or synthesis of a substance.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Gregory Zayia on September 27, 2006, a provisional election was made without traverse to prosecute Invention I, claims 1-17. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear if the filter in claim 14 is part of the claimed instrument. It is also not clear whether the filter is a different element from the porous membrane. For examination purposes, the filter is interpreted to be different from the porous membrane. (Applicant can overcome this rejection by amending the claim so that it reads –further comprising a filter, wherein the filter is...--)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-12, 14, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell et al., 6,168,914.

As to claim 1, Campbell et al. teach an instrument for forming an immobilized sample on a porous membrane comprising:

a first plate (24, for example, the topmost plate 24 in fig. 4) comprising a first connector (i.e., the wells/reaction vessels 30 at the periphery of the plate, in fig. 4) and a first region (i.e., the wells/reaction vessels 30 within that plate in fig. 4, other than the well/s reaction vessels 30 at the periphery of the plate) provided with a plurality of through-holes (see fig. 4 and col. 13, lines 10-11); and

a second plate (24, for example, the plate 24 beneath the topmost plate 24 in fig. 4) comprising a second connector (i.e., the wells/reaction vessels 30 at the periphery of the plate, in fig. 4) configured for engaging the first connector (see fig. 4 showing that the wells stack on top of each other) and a second region (i.e., the wells/reaction vessels 30 within that plate in fig. 4, other than the well/s reaction vessels 30 at the periphery of the plate) provided with a plurality of through-holes (see fig. 4 and col. 13, lines 10-11);

wherein a porous membrane (frit 34, see col. 13, line 11) is interposed between the first region and the second region by engagement of the first connector and the second connector. It is noted that while Campbell et al. do not state that the frits (34) are porous membranes, Campbell et al. nevertheless disclose that fluid flows through the frits (see col. 13, lines 35-46, disclosing that reagents are circulating through the

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vertical columns of reaction vessels 30), and the frits are disclosed to be thin (see fig. 14). Thus, the frits are deemed to be porous membranes. Moreover, Campbell et al. disclose another embodiment wherein wells (110) are filled with beads, and wherein each well is provided with a divider 112, such as a frit or membrane (col. 16, lines 25-27). Thus, Campbell et al. here equate a frit with a membrane.

As to claim 2, the first connector detachably engages the second connector (see fig. 4. showing that the wells stack on top of each other).

As to claim 3, each of the through-holes provided in the first region confronts a corresponding through-hole provided in the second region when the first connector is engaged with the second connector (see fig. 4, disclosing the wells to be stacked on top of each other).

As to claim 4, each of the through-holes provided in the first region shares an axis with each of the through-holes provided in the second region (see fig. 4, disclosing the wells to be stacked on top of each other).

As to claim 5, the porous membrane and the through-holes provided in the first region form wells (30, see col. 13, line 7, and fig. 4) when the first connector is engaged with the second connector.

As to claim 6, the wells corresponding to each of the through-holes provided in the first region are formed so as to be substantially watertight (see col. 3, lines 17-21, and col. 19, lines 26-30, disclosing a fluid-tight seal to prevent cross-contamination between reaction vessels)

As to claim 8, the through-holes provided in the first region are arranged in a matrix pattern in the first region, and wherein the through-holes provided in the second region are arranged in a matrix pattern in the second region (see figs. 3 and 4).

As to claim 9, the first plate further comprises a third region (i.e., the region containing the first connector as described in claim 1 above) circumscribing the first region, such that the first connector is provided in the third region, and wherein the second plate further comprises a fourth region (i.e., the region containing the second connector as described in claim 1 above) circumscribing the second region, such that the second connector is provided in the fourth region.

As to claim 10, the first connector and the second connector are formed as a combination of fitted concavities and convexities (see fig. 4 disclosing the convexities of the wells of the first plate fitting with the concavities of the wells of the second plate, i.e., the plate below).

As to claim 11, the first connector comprises concavities or convexities provided in a periphery of the first region, and wherein the second connector comprises convexities or concavities provided in a periphery of the second region (see fig. 4, wherein the wells at the periphery of the topmost plate are considered to be the first connector and the wells surrounded by the peripheral wells are considered to be the first region of the first plate, and similarly with respect to the second plate, as described above regarding claim 1.)

As to claim 12, the concavities and the convexities have a close fitting tolerance (see fig. 4).

As to claim 14, Campbell et al. teach an instrument for forming an immobilized sample on a porous membrane comprising:

a first plate (76, see fig. 5) comprising a first connector (for example, the periphery of plate 76) and a first region (i.e., the region with the openings) provided with a plurality of through-holes (see fig. 5); and

a second plate (78) comprising a second connector (for example, the periphery of plate 78) configured for engaging the first connector (see col. 4, lines 34-41, disclosing that the end plates, i.e., 76 and 78, are compressed or clamped together) and a second region (i.e., the region with the openings) provided with a plurality of through-holes (see fig. 5);

wherein a porous membrane (72) is interposed between the first region and the second region by engagement of the first connector and the second connector. It is noted that while Campbell et al. do not state that the membranes are porous, Campbell et al. nevertheless disclose that fluid flows through the membranes (see col. 14, lines 55-59). And more specifically as to claim 14, Applicant further claims that a filter is interposed between the first region and the second region by engagement of the first connector and the second connector. Campbell et al. teach that there is more than one membranes (72), (see col. 14, lines 42-48). One membrane (72) is deemed to be Applicant's claimed "porous membrane", and another membrane (72) is deemed to be Applicant's claimed filter.

As to claim 16, Applicant claims that the immobilized sample comprises immobilized protein. Campbell et al. disclose this by teaching that the solid supports

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may be used for synthesis of polypeptides (col. 21, lines 62-65). (Campbell et al. also disclose in column 23, line 40, use of the invention to synthesize compounds and for subsequent enzymatic assays). It is noted that Applicant does not specify as to what the sample is immobilized.

As to claim 17, Campbell et al. teach an instrument for forming an immobilized sample on a porous membrane comprising:

a first plate (24, for example, the topmost plate 24 in fig. 4) comprising a first region (i.e., the region with the wells/reaction vessels 30 on the plate, in fig. 4) provided with a plurality of through-holes; and

a second plate (24, for example, the plate 24 beneath the topmost plate 24 in fig. 4) comprising a connector (i.e., the wells/reaction vessels 30 at the periphery of the plate, in fig. 4) configured for engaging the first plate and comprising a second region (i.e., the wells/reaction vessels 30 within that plate in fig. 4, other than the well/s reaction vessels 30 at the periphery of the plate) provided with a plurality of through-holes;

wherein a porous membrane (frit 34, see col. 13, line 11) is interposed between the first region and the second region by engagement of the connector and the first plate. It is noted that while Campbell et al. do not state that the frits (34) are porous membranes, Campbell et al. nevertheless disclose that fluid flows through the frits (see col. 13, lines 35-46, disclosing that reagents are circulating through the vertical columns of reaction vessels 30), and the frits are disclosed to be thin (see fig. 14). Thus, the frits are deemed to be porous membranes. Moreover, Campbell et al. disclose another

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embodiment wherein wells (110) are filled with beads, and wherein each well is provided with a divider 112, such as a frit or membrane (col. 16, lines 25-27). Thus, Campbell et al. here equate a frit with a membrane.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al., 6,168,914.

Campbell et al. teach the invention substantially as claimed (see above).

Campbell et al. disclose the wells of the plates to be stacked on top of each other in figure 4. Campbell et al. teach clamping the plates together so that there is a fluid tight seal (col. 3, lines 18-20), and that the plates may be formed of elastic material to deform slightly under compression to form a seal (col. 19, lines 26-30). However, Campbell et al. do not teach that the close fitting tolerance is between the plates is p6/H7. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, Campbell et al. teach the general conditions of the

claim and the close fitting tolerance being p6/H7 is within an optimum or workable range and thus its discovery involves only routine skill in the art under *In re Aller*.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Campbell et al., 6,168,914, in view of Fernwood et al., 4,493,815.

Campbell et al. teach the invention substantially as claimed (see above regarding claim 1), except for each of the through-holes formed in the first region and each of the through-holes formed in the second region being substantially ovoid in shape.

However, Fernwood et al. teach a test plate assembly providing discrete wells to permit a multitude of biochemical tests to be run simultaneously. Fernwood et al. teach that the typical array will comprise circular wells, and that other examples include oval or slot-shaped wells with associated apertures of appropriate shape (col. 2, lines 60-64). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the Campbell et al. through-holes in the form of an oval or slot-shape as taught by Fernwood et al. because Fernwood et al. teach that test plate with discrete wells for running biochemical tests can be circular in shape or oval in shape. That is, Fernwood et al. teach that wells that are circular in shape are functional equivalents to wells that are oval (i.e., ovoid) in shape for purposes of running biochemical tests, and thus it would have been obvious to one of ordinary skill in the art to provide an oval shaped well in the Campbell et al. invention.

Claim 15 is rejected under 5 U.S.C. 103(a) as being unpatentable over Campbell et al., 6,168,914, in view of Hinckley, 4,833,087.

Campbell et al. teach the invention substantially as claimed (see above regarding claim 14), except for the filter comprising a filter paper. Campbell et al. teach that the membranes may be formed of various materials and give examples of such materials (see col. 3, lines 35-39 and col. 14, line 60 – col. 15, line 11)). Campbell et al. teach that the membranes provide a solid support for synthesis of materials and subsequent use for assays (col. 4, lines 14-15 and col. 14, lines 48-50 and col. 23, lines 24-44). However, Campbell et al. do not specifically list filter paper as an example of a material that can be used as the membrane of the invention.

Hinckley however teaches a device for storage of a reagent for a reaction and that also provides for a reaction chamber for the reaction (col. 1, lines 6-8), wherein the device includes a material such as filter paper or porous membrane or the like constructed to retain on that material a reaction product yet to be formed (col. 3, lines 3-7). Because Hinckley teaches that a filter paper can serve in place of a porous membrane to provide a solid support for a material to be formed and because Campbell et al. do not limit the type of material that can be used to form the porous membrane of the invention, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide filter paper as the porous membrane in the Campbell et al. invention. That is, Hinckley teaches that a filter paper is a functional equivalent to a porous membrane as a solid support for a reaction product to be formed and thus it

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would have been obvious to one of ordinary skill to utilize a filter paper as taught Hinckley as the porous membrane in the Campbell et al. invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Ann Lam 9/28/06